C. Remarks

The claims are 2-14 and 16-41, with claims 2, 19 and 20 being independent. Claims 2 and 7 have been amended to more clearly define the intended invention. Support for the amendment to claim 2 may be found on page 3, paragraph [0031] of the published specification, U.S. Patent Application Publication No. 2005/0136104 (the "104 publication"). Applicants submit that no new matter has been added. Reconsideration of the present claims is respectfully requested.

Claims 2-14 and 16-18 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for use of the term "substantially ungelatinized." Applicants respectfully traverse the rejection.

The claims have been carefully reviewed and amended as deemed necessary to ensure that they conform fully to the requirements of Section 112, second paragraph, with special attention to the points raised in the Office Action. Specifically, claim 2 has been amended to replace "substantially ungelatinized" with the description that the hydroxypropylated starch is at least 50% ungelatinized. It is believed that the rejection under Section 112, second paragraph, has been obviated, and its withdrawal is therefore respectfully requested.

Claims 2-14 and 16-18 stand rejected under 35 U.S.C. §103(a) as being obvious over Borkan (U.S. Patent No. 4,935,243) in view of Lin (U.S. Patent Publication No. 2003/0215495), Sano (U.S. Patent No. 6,280,767) and Stroud (U.S. Patent No. 5,554,385). Applicants respectfully traverse this rejection.

The present invention is directed to a gelatin capsule formed from a capsule film having a thickness not exceeding 0.030 inches, and a capsule shell having an end

composition comprising at least one gelatin, plasticizer and at least one hydroxypropylated starch, which is at least 50% ungelatinized. By virtue of this constitution, it is possible to provide high water content, chewable soft gelatin capsules with improved organoleptic properties. The present invention combines a multifactorial approach in modifying both the material of the capsule and the fabrication method of the encapsulation process in order to maximize the organoleptic properties of the capsule and the stability thereof. This includes manipulation of the origin, bloom strength, melting points and mixtures of gelatins, the use of hydroxypropylated, at least 50% ungelatinized starch as a water retention agent, the fabrication of thinner than expected gelatin films for use in the encapsulation process, only partial drying to a high end water content and dusting of the capsules with an anti-stickiness surface treatment agent. Some of the important features include:

- The use of a hydroxypropylated, at least 50% ungelatinized starch as a water retention agent. This allows for a higher water content in the shell, which in turn provides for a softer capsule shell and more rapid hydration and swelling of the shell in contact with saliva in the mouth, which in turn provides for better mouth feel and more rapid dissolution/disintegration of the shell and release of the capsule contents.
- A unique aspect of the presently claimed invention is that the gelatin capsules are able to maintain both robust seals and thin walls (in accordance with the newly added claim limitation) by virtue of the combination of stronger gelatins and hydroxypropylated, at least 50% ungelatinized starch. Page 3, paragraph [0033].

- The use of a higher bloom strength gelatin, which increases the strength of the ribbon, and the capsule seals produced from this ribbon, which in turn allows for the use of a thinner ribbon to manufacture the capsule shell, which in turn provides for more rapid dissolution/disintegration of the ribbon in the mouth and a lower shell to fill ratio in the finished capsule.

Further, Applicants' capsule of the presently claimed invention is dried to a relatively high water content, i.e, 9.5% to 11.5%, unlike traditional gelatin capsules, which are typically dried to 6% to 8% water. Pages 3-4, paragraph [0035] of the '104 publication. This higher water content has improved mouthfeel and chewability without the typical drawbacks of higher water content, like stickiness or clumping together. Page 4, paragraph [0035] of the '104 publication. This advance over the prior art is achieved through a process of lightly tumble drying the capsules, and in some case, using a dusting agent. Page 4, paragraph [0035]-[0036] of the '104 publication. This surface treatment process post-encapsulation minimizes stickiness and clumping of the capsules, which might otherwise occur because of the high water content of the shell relative to more conventional softgel capsule formulations.

Borkan discloses a chewable softgel capsule containing gelatin and a plasticizer (including glycerol); however, as noted by the Examiner, Borkan does not teach or suggest 1) the inclusion of a modified starch, such as hydroxypropylated starch, 2) that the starch is at least 50% ungelatinized, or 3) a capsule having a film thickness not exceeding 0.030 inches.

The hydrogenated starch hydrolysate taught in Borkan (described at column 4, line 5, to column 5, line 11) is characterized as a mixture of sugars, hydrogenated sugars,

polyols and sugar alcohols. This component in no way equates with the high molecular weight, polymeric starch employed in the subject invention.

Additionally, Borkan fails to disclose or suggest the end water content of the presently claimed invention. In fact, Borkan teaches away from said water content by disclosing that the water content of the shell is between 15%-30% to aid in its rapid dissolution. Column 3, lines 59-63.

The Examiner has alleged that Borkan discloses bloom strengths in the range 60-300. However, Borkan fails to suggest the benefits conferred by use of the specific types of gelatins, including the importance of high bloom strength to increase ribbon strength, capsule seal strength and resistance to deformation at higher temperatures, which are all important attributes of the present invention. Therefore, Applicants submit that Borkan does not render the present invention obvious.

Lin is cited by the Examiner for its disclosure of a soft capsule shell comprising modified starch, such as hydroxypropylated starch, and plasticizer, such as glycerin, sorbitol and polyethylene glycol. However, Lin does not teach a chewable softgel capsule or the use of hydroxypropylated starch in combination with gelatin, as disclosed in the presently claimed invention. As evidenced on page 3, paragraphs [0045]-[0046], Lin clearly teaches softgel ribbons made with iota carrageenan in combination with hydroxypropylated starch as the gelling systems. The capsule material containing iota carrageenan and hydroxypropylated starch are further taught on page 7, paragraphs [0069]-[0070]. Furthermore, paragraph [0045] of Lin incorporates by reference Tanner et al., U.S. Patent No. 6,340,473, which was previously relied on by the Examiner. As previously noted by Applicants in response, since the disclosure of Tanner states that the intention is

to obviate the requirement for gelatin, Tanner teaches away from the present invention, wherein modified starch and plasticizer are combined with gelatin. Since Lin relies on Tanner, it too teaches away from the present invention, and one of ordinary skill in the art would not be motivated to combine Lin with Borkan to achieve the subject invention

The Examiner states that the fill formulation systems of Lin have improved stability for the incorporated drug. However, the multifactoral approach of the present invention serves to enhance the properties and physical stability of the shell, not the fill.

Furthermore, Lin fails to teach or suggest 1) a capsule having a film thickness not exceeding 0.030 inches, 2) the starch being at least 50% ungelatinized, or 3) the inclusion of high bloom strength gelatin, the combination of which enhances the organoleptic properties and physical stability of the shell. Accordingly, Applicants submit that Lin fails to remedy the deficiencies of Borkan.

Sano and Stroud, likewise, do not remedy the deficiencies of Borkan in view of Lin. Sano is cited for allegedly teaching a chewable soft gelatin capsule comprising gelatin, plasticizers and water soluble starch. Applicants respectfully disagree with the Examiner's characterization of Sano. While the Examiner refers to the inclusion of a water soluble starch, citing column 3, line 60 of Sano, Applicants respectfully submit that column 3, line 60 refers to starch as a possibility for component (C), which is preferably a water-insoluble cellulose (see column 2, line 19), and does not find any evidence that the starch is water soluble. Furthermore, starch is merely listed as a possible option for component (C) in Sano and, in fact, is not specifically disclosed in any of the exemplary systems in the specification.

Stroud discloses soft gelatin capsules wherein some of the gelatin is replaced by starch. However, Stroud fails to teach or suggest using a hydroxypropylated starch or wherein the starch is over 50% ungelatinized, as part of the capsule composition. Stroud is limited to a disclosure of starches of high amylose content. While Stroud discloses a capsule wall having a thickness of about 0.030 inches, the present invention claims a capsule wall not exceeding 0.030 inches. In addition, unlike the presently claimed invention, the capsule shell of Stroud has a 6% water content.

Therefore, Applicants submit that neither Sano nor Stroud discloses or suggests the gelatin capsule of the claimed invention, and, specifically, 1) use of a hydroxypropylated starch, 2) the hydroxypropylated starch being at least 50% ungelatinized, 3) a capsule having a final end water content of 9.5% to 11.5%, 4) a capsule having a film thickness not exceeding 0.030 inches, or 5) the inclusion of high bloom strength gelatin, the combination of which enhances the organoleptic properties and physical stability of the shell

In sum, the presently claimed invention is not rendered obvious by the cited references, whether considered separately or in any permissible combination. The references simply do not teach the combination of features of the presently claimed invention, which, as further described above, results in a capsule shell have improved properties, including mouth feel, dissolution/disintegration of the shell and stability. For at least the reasons set forth above, Applicants submit that the present invention is not rendered obvious and respectfully request withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

/Elizabeth F. Holowacz/
Elizabeth F. Holowacz
Attorney for Applicants
Registration No.: 42,667

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200